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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,083	08/31/2001	Steven M. Lefkowitz	10010381-1	1180

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,083

Applicant(s)

LEFKOWITZ ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 27-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-26 and 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (Claims 7-15, 25, and 44-47) *in relation to Group III through Group VI and without traverse in relation to Group I* in Paper No. 5 is acknowledged. The traversal is on the ground(s) that Group III (Claims 16-24 and 26) should be joined with Group II because they have not been shown to have different modes of operation, different functions, or different effect. Group IV (Claims 27-29) should be joined with Group II because all the claims of Group IV are dependent on Claim 25 of Group II. Group V (Claims 30-32) and Group VI (Claims 33-35) should be joined with Group III because all the claims of Group V and Group VI are dependent on Claim 26 of Group III.

In regard to rejoining of Group III with Group II, this is found persuasive because upon reevaluation of the restriction between Group II and Group III made of record. The method steps of Groups III do not distinguish them from Group II as independent and distinct invention. But rather they are an added limitation. Therefore, the restriction requirement is modified to the extent that Group III now rejoined with Group II.

In regard to rejoining of Group IV with Group II, this is not found persuasive because Group IV claims a method for detecting the presence of an in a sample while Group II defines a method of producing an array. The "method of producing an array" of Group II involves different method steps than the "method for detecting the presence of an in a sample" of Group IV. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group II would involve a determination of the patentability of the method step of contacting the surface with two different polymer ligands to

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covalently bond the polymer ligands to the substrate and produce an array while a patentability determination for Group IV would involve a consideration of the patentability of the method step of detecting any binding complexes on the surface. These considerations are very different in nature. Further, the law has long been established that dependent inventions (frequently termed related inventions) such as claims 27-29 depend directly or indirectly from claim 25 may be properly divided if they are, in fact, "distinct" inventions, even though dependent. See MPEP § 802.01.

In regard to rejoining of Group V with Group III, this is not found persuasive because Group V claims a hybridization assay while Group III defines a method of producing an array. The "method of producing an array" of Group III involves different method steps than the "a hybridization assay" of Group V. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group III would involve a determination of the patentability of the method step of converting the olefin functional groups to reactive functional groups that produce covalent bonds while a patentability determination for Group V would involve a consideration of the patentability of the method step of detecting the hybridization pattern. These considerations are very different in nature. Further, the law has long been established that dependent inventions (frequently termed related inventions) such as claims 30-32 depend directly or indirectly from claim 26 may be properly divided if they are, in fact, "distinct" inventions, even though dependent. See MPEP § 802.01.

In regard to rejoining of Group VI with Group III, this is not found persuasive. Because these inventions are apparatus and process, the apparatus as claimed can be used to practice another and materially different process such as the method of protein synthesis. Additionally,

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different patentability considerations are involved for each group. For example, a patentability determination for Group VI, the kit, would involve a determination of the patentability of the combination of components independent of how they are used (i.e. for any method of use).

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1-6 and 36-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

3. Claims 27-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

4. Group III (Claims 16-24 and 26) is rejoined with Group II (Claims 7-15, 25, and 44-47). Therefore, Claims 7-26 and 44-47 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 7-14, 16-23, 25-26, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) in view of Wang et al. (US Patent 5,922,617).

Sundberg et al. discloses a method and an array of immobilized peptides, oligonucleotides, or other small organic molecules on a variety of derivatized solid substrate (col. 1, lines 64-67 to col.2, lines 1-10; col. 9, lines 43-53). The method comprises a solid substrate that is reacted with a derivatization reagent having a reactive site (functional group) (col. 10, lines 55-66; figure 8-11). The reactive site on the derivatized substrate would covalently attached to the linking molecules such as peptides, oligonucleotides, or nucleic acids (col. 11, lines 49-62; col. 4, lines 43-56). Groups that are suitable for attachment of the linking molecules include ester, amine, and aldehyde (col. 11, lines 59-62; figure 8). The array is examined for the relative amount of specific and non-specific binding between the substrate on a solid support and a receptor by reacting the array with a sample (col. 23, lines 1-15).

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The method of Sundberg et al. does not expressly disclose that different polymer ligands are attached on the surface of the array and transmitting the data to a remote location.

Wang et al. discloses methods and devices for rapidly screening a large number of events. The devices comprise of a microarray of bound components and the methods comprise of preparing the microarray (col. 2, lines 60-65). The method comprises of modifying the surface of the solid substrate by the introduction of functionalities, which would react with the bound components (col. 3, lines 17-25 and 38-45). The bound components include nucleic acids and proteins (col. 3, lines 56-58; col. 5, lines 7-10). The microarray comprise of a plurality of different components (col. 2, lines 60-65). The method of Wang et al. further comprise of assaying the microarray by detecting the signal produced using a disk scanner (col. 10, lines 16-25 and 50-62). The scanner would be connected to the computer through which the data is collected and process (col. 12, lines 59-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an array of different polymer ligands on the surface of the substrate and transmitting the data to a remote location as taught by Wang et al. in the method of Sundberg et al. One of ordinary skill in the art would have been motivated to include an array of different polymer ligands on the surface of the substrate in the method of Sundberg et al. for the advantage of detecting multiple analytes. Since both Sundberg et al. and Wang et al. disclose a method of attaching polymer ligands onto the surface of the solid substrate by modifying the surface of the solid substrate by the introduction of functionalities, which would react with the bound components (Sundberg: col. 10, lines 55-66; figure 8-11; Wang: col. 3, lines 17-25 and 38-45).

8. Claims 7, 15-16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) in view of Wang et al. (US Patent 5,922,617) as applied to claims 7-14, 16-23, and 25-26 above, and further in view of Gleason et al. (US Patent 5,561,097).

The methods of Sundberg et al. and Wang et al. applied for the reasons discussed above.

The method of Sundberg et al. as modified by Wang et al. does not expressly disclose that the functional group is imidazolyl carbamates.

Gleason et al. discloses a method of covalently coupling ligands onto a support (col. 5, lines 24-29). The method comprises of a reactive support, which comprise of a reactive functional group that covalently couple with the desired ligand. A number of useful particles and membranes are commercially available which contain reactive functional groups such as aldehydes and imidazolyl carbamates (col. 5, lines 46-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the functional group in the method of Sundberg et al. as modified by Wang et al. with the imidazolyl carbamates functional group of Gleason et al. One of ordinary skill would be motivated because Sundberg et al., Wang et al., and Gleason et al. disclose the methods of attaching ligands onto the surface of the solid substrate (Sundberg: col. 10, lines 55-66; figure 8-11; Wang: col. 3, lines 17-25 and 38-45; Gleason: col. 5, lines 24-29). Further, Gleason et al. disclosed that there are a number of commercially available solid supports, which contain reactive functional groups such as aldehydes and imidazolyl carbamates (col. 5, lines 46-

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51). The choice of one particular type of functional group on a support is dependent on the availability and accessibility of that functional group.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 7, 14, 16, and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 6-8 of U.S. Patent No. 6,319,674 (Fulcrand et al.) in view of Wang et al. (US Patent 5,922,617).

The claimed method of Fulcrand et al. is obvious over the presently claimed invention because the method of Fulcrand et al. discloses a method of immobilizing a substance such as ligand or polynucleotide to a surface by treating the linking group on the surface and attaching the substances by means of amine functionality as claimed by the presently claimed invention.

However, the method of Fulcrand et al. does not expressly disclose that different polymer ligands are attached on the surface of the array. Wang et al. disclose a method of immobilizing different substances onto a surface by modifying the surface of the solid substrate by the

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introduction of functionalities, which would react with the bound components (col. 2, lines 60-65; col. 3, lines 17-25, 38-45, and 56-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an array of different polymer ligands on the surface of the substrate as taught by Wang et al. in the method of Fulcrand et al. Since both Fulcrand et al. and Wang et al. disclose a method of attaching polymer ligands onto the surface of the solid substrate by modifying the surface of the solid substrate by the introduction of functionalities, which would react with the bound components (Fulcrand: Claim 1, and 6-8; Wang: col. 3, lines 17-25 and 38-45).

Therefore, the method of Fulcrand et al. modified by Wang et al. would be obvious over the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct

December 23, 2002


PADMA SHRI PONNALURI
PRIMARY EXAMINER